

**510(k) SUMMARY**

K041737

Submitter Information: TOTOKU ELECTRIC CO., LTD.  
300 Oya, Ueda  
Nagano 386-0192 Japan

Contact Person: Mikio Hasegawa, General Manager  
Email: [hasegawam@totoku.co.jp](mailto:hasegawam@totoku.co.jp)  
Tel: +81.268.34.5469  
Fax: +81.268.34.5548

Date Prepared: June 22, 2004

Device Name: 5M Monochrome Digital Mammography LCD Monitor ME511L  
(MDL2105A)

Common Name: ME511L, MDL2105A

Classification Name: Class II  
(Part 892 Radiology Devices  
Sec. 892.2050 Picture Archiving and Communication System)

Predicate Device: Barco MGD 521M Digital Mammography Display (K033859)

Device Description: ME511L (MDL2105A) is a 21.3-inch 5 megapixel monochrome LCD display whose display resolution is 2560x2048 (QSXGA), supporting DVI (digital visual interface).

Intended Use: ME511L (MDL2105A) is intended for use with Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians, including digital mammography.

Substantial Equivalence: ME511L employs a different display system from Barco's MGD521M (K033859), but maximum resolution and luminance are the same.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 13 2004

Mr. Mikio Hasegawa  
General Manager  
Totoku Electric Co., Ltd.  
MM Company, Design Group  
300 Oya, Ueda,  
Nagano, 386-0192  
JAPAN

Re: K041737  
Trade/Device Name: 5M Monochrome Digital  
Mammography LCD Monitor ME511L (MD2105A)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving  
and communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: June 23, 2004  
Received: June 28, 2004

Dear Mr. Hasegawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

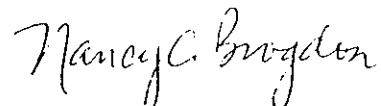
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

|                                  |                |
|----------------------------------|----------------|
| 8xx.1xxx                         | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx       | (301) 594-4654 |
| Other                            | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number:

Device Name: 5M Monochrome Digital Mammography LCD Monitor ME511L (MDL2105A)

Indications for Use:

ME511L (MDL2105A) is intended for use with the Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians, including digital mammography.

Prescription Use

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K041737